

# EXHIBIT X

# ETHICON

a *Johnson & Johnson* company

January 8, 2002

To: M. D'Aversa

Re: Biocompatibility Risk Assessment for GyneMesh PROLENE Soft Mesh

GyneMesh PROLENE Soft Mesh is comprised of the same mesh as PROLENE Soft Mesh. As such, the assessment of biocompatibility will be addressed by reference to the formal strategy for biocompatibility for PROLENE Soft Mesh entitled "Biocompatibility Risk Assessment for Soft PROLENE Mesh - Revised, dated 12/2/99 (see attached). Ref.: Soft PROLENE Mesh, DHF #DH0494.

In summary, the preclinical study results and the extensive clinical experience with current PROLENE mesh, and natural and blue PROLENE suture demonstrate that this polypropylene base material, with or without copper phthalocyanine blue pigment, is intrinsically safe and without significant adverse effects for patients. It is considered that GyneMesh PROLENE Soft Mesh manufactured with PROLENE Soft Mesh will result in the same level of safety demonstrated by the currently marketed products, and no further preclinical testing is necessary.



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156 of 258